

Montana Laboratory Sentinel



Updates from the MT Laboratory Services Bureau
800-821-7284 www.lab.hhs.mt.gov

2/25/2011



PATIENT SAFETY IS PRIORITY #1

To keep in line with patient safety initiatives, as of March 15, 2011, the Montana Public Health Laboratory (MTPHL) will require that all submitted specimens be labeled with **two identifiers**. The identifiers can be hand written or a computer generated label, and may include a full name and birth date, a full name and facility identifier, or any combination that will accurately identify the patient specimen and match it to the requisition form. Specimens received after March 15, 2011 that are not properly labeled with two identifiers will be rejected. If you have any questions regarding this implementation, please call Debbie at 406-444-5970.

Hepatitis C Testing Changes

Montana Public Health Laboratory (MTPHL) was recently notified that Hepatitis C Virus (HCV) Confirmatory Testing by RIBA will be unavailable for an indeterminate period of time due to a manufacturer's shortage of reagent. RIBA testing confirms the presence of HCV antibody and will rule out false positive results on specimens that have a sample/cutoff ratio of less than 3.8 during the HCV antibody screen. Due to the lack of availability of RIBA testing, MTPHL will be turning out these low level results with the following comment:

The sample/cutoff ratio of this test result is less than 3.8 and by CDC recommendations, needs confirmatory testing to rule out a potential false positive. The Hepatitis C RIBA testing is currently unavailable for an indeterminate period of time due to a manufacturer's shortage of reagent. If this person is considered high risk or has signs and symptoms of active infection, a Hepatitis C Virus RNA by PCR is recommended as an alternative.

Once RIBA testing becomes available, MTPHL will return to its usual practice of confirming low level results. If you have any questions, contact Debbie Gibson at 406-444-5970.

The Communicable Disease Epidemiology Program Weekly Update for MMWR reporting week six.

This issue contains information about:

-Influenza season update

-shigellosis

-shigellosis versus norovirus: how to differentiate

To read the update visit:

http://www.dphhs.mt.gov/PHSD/epidemiology/documents/CDWeeklyUpdateWk_06.pdf

Newborn Screening for Cystic Fibrosis: Changes in timing and ranges

A statewide expert consultation on Cystic Fibrosis (CF) screening was held in January 2011, and as a result, the age-adjusted normal ranges used for Immunoreactive Trypsinogen (IRT), the screening marker for CF on the Montana Newborn Screening Panel, will change. Specimens received at the MTPHL on March 14, 2011 will be interpreted using the new ranges.

Background: IRT is elevated in newborns with CF due to a pancreatic dysfunction. When an elevated IRT level above a certain age-adjusted cutoff is reported, a second screen is requested. IRT levels decrease in unaffected babies during the first weeks of life, but remain relatively high in babies with CF. If the IRT is elevated in both the initial and repeat dried blood specimens, the baby's primary care provider is notified that further diagnostic testing for CF is indicated. *Most babies with an abnormal IRT on the initial specimen will not have CF.* For example, IRT levels may be falsely elevated in premature or sick infants.

Changes: The MTPHL normal range for IRT on the first screen will remain less than or equal to 100 ng/mL, but the range will change to less than or equal to 80 ng/mL when the infant is greater than 7 days of age at collection. If the infant is greater than 21 days of age at collection, the normal range will be reduced to less than or equal to 70 ng/mL. The recommended time frame for collecting the second screen has been shortened from 3 weeks to any time after 7 days, to reduce the delay between an out-of-range first screen and the repeat screen. This change should reduce anxiety for families and providers. This change also allows for an earlier referral for diagnostic CF testing if the second screen is out-of-range and an earlier treatment if CF disease is confirmed. Blood spots from infants with birth weights less than 1500 grams and two elevated IRTs will be automatically reflexed to a CF DNA Mutation panel.

Montana's CF screening protocol is designed to detect as many newborns with CF as possible, but no screening test is perfect. *Infants with symptoms suggesting CF (recurrent respiratory problems, failure to thrive, etc) should receive further diagnostic testing, even if the newborn IRT screen for CF was normal.*

To learn more about [Cystic Fibrosis](#) and the testing used to help diagnosis this disease, visit the DPHHS Newborn Screening website. If you have any questions, please contact Linda Beischel, Newborn Screening Follow-up Coordinator at 800-821-7284, ext 0984 or directly at 406-444-0984.